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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/540,187

02/13/2006

Christian Noe

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EXAMINER

CHUNG, SUSANNAH LEE

ART UNIT

PAPER NUMBER

1626

MAIL DATE

DELIVERY MODE

07/03/2008

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/540,187	NOE ET AL.	
	Examiner	Art Unit	
	SUSANNAH CHUNG	1626	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 13 February 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 13-32 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 13-32 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>8/31/05</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claims 13-32 are pending in the instant application. Claims 1-12 are canceled by preliminary amendment.

Priority

This application is a 371 of PCT/EP03/14432, filed 12/18/2003.

Acknowledgment is made of applicant's claim for foreign priority under 35 U.S.C. 119(a)-(d) by application no. A1896/2002 filed in the Austrian Patent Office on 12/18/2002, which papers have been placed of record in the file. The application names an inventor or inventors named in the prior application.

Information Disclosure Statement

The information disclosure statement (IDS), filed on 8/31/05 has been considered. Please refer to Applicant's copy of the 1449 submitted herewith.

Claim Rejections - 35 USC § 112, 2nd paragraph

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 13-32 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The claims are rejected as being incomplete for omitting essential steps, such omission amounting to a gap between the steps. See MPEP §2172.01. The omitted steps are the reagents used and specific steps of preparing the compounds recited in Claim 1. For example, Applicants need to include specific reagents and steps as described in Example 1, page 15 of the

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specification. Currently claim 1 contains no process steps. A claim is indefinite where it merely recite a use without any positive steps delimiting how the use is actually practiced.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 13-32 are rejected under 35 U.S.C. 102(b) as being anticipated by Noe, et al (U.S. Pat. No. 6,307,060 B1 ('060 Patent)).

Applicants claim a process of making substituted glycopyrronium bromide or iodide compounds, but do not provide any process steps. Therefore, the claims will be treated as product by process claims. “[E]ven though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process.” *In re Thorpe*, 777 F.2d 695, 698, 227 USPQ 964, 966 (Fed. Cir. 1985). MPEP 2113.

Noe discloses compounds in claim 1 that anticipate the instantly claimed compounds of the product-by-process claim. Therefore, claims 13-32 are rejected as claiming the same product as the product of Noe. (See '060 Patent column 17, claim 1.)

Even if the instant claims were not treated as product-by-process claims, the claims would be anticipated by the process disclosed by Noe in claims 9, 10 and 15-18.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 13-32 are rejected under 35 U.S.C. 102(b) as being unpatentable over Noe, et al (U.S. Pat. No. 6,307,060 B1 ('060 Patent)).

Applicant's instant elected invention teaches a process for preparing a particular stereoisomer of glycopyrronium bromide or iodide.

Determination of the scope and content of the prior art (MPEP § 2141.01)

Noe teaches a process for preparing a particular stereoisomer of glycopyrronium bromide or iodide.

Ascertainment of the difference between the prior art and the claims (MPEP § 2141.02)

The difference between the prior art of Noe and the instant claims is that the prior art claims a broader class of compounds than the instant application.

Finding of prima facie obviousness - rationale and motivation (MPEP § 2142-2413)

One skilled in the art would have found the claimed process prima facie obvious because the instantly claimed process and the process in Noe are describing the same process, i.e. the process of preparing a particular isomer of glycopyrronium bromide or iodide.

It should be noted that the process disclosed in the instant application and the process disclosed in the prior art are essentially the same and one of ordinary skill in the art would be able to obtain the instantly claimed compound by the process disclosed in the prior art and vice versa. It is well established that change in temperature, concentration, or both is not a patentable modification in the absence of unexpected results which is different in kind and not degree. In re Aller, 105 USPQ 233. In addition, discovery of an optimum value of a result effective variable is not patentable if such discovery is within skill in the art. A prima facie case of obviousness may be rebutted in optimizing a variable only when results are unexpectedly good. In re Boesch, 205 USPQ 215. Therefore, the claimed process is prima facie obvious in light of the prior art unless applicant can show a difference that results in unexpectedly good results.

It has long been the practice in the chemical and pharmaceutical arts to produce compounds in the stereoisomer form. There is no patentable distinction in the concept of a chemical compound in stereoisomer or enantiomer form over the compound itself. Changing the form, purity or other characteristic of an old product does not render the novel form patentable where the difference in form, purity or characteristic was inherent in or rendered obvious by the prior art. In re Cofer, 148 U.S.P.Q. 268 (CCPA 1966). Therefore, absent a showing of unobvious and superior properties, the instantly claimed process would have been suggested to one skilled in the art.

Obviousness Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 13-32 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over Claims 9, 10, and 15-18 of U.S. Patent Num. 6,307,060 ('060 Patent).

Instant claim 1 claims a process for preparing a stereoisomer of glycopyrronium bromide or iodide.

The '060 Patent claims a process for preparing a stereoisomer of glycopyrronium bromide or iodide.

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Although the conflicting claims are not identical, they are not patentably distinct from each other because one of ordinary skill in the art would recognize that the process claimed in the '060 Patent is the same as the process disclosed in the instant application. A timely filed terminal disclaimer will overcome this rejection.

Telephone Inquiry

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Susannah Chung whose telephone number is (571) 272-6098. The examiner can normally be reached on M-F, 8am-5pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph McKane can be reached on (571) 272-0699. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/REI-TSANG SHIAO /
Primary Examiner, Art Unit 1626

Susannah Chung, July 1, 2008